

### **REMARKS**

As an initial matter, the Office Action indicates that the present application is involved in litigation and that no extensions of time will be permitted during prosecution of the application. It is respectfully submitted that the present application based on U.S. Pat. No. 6,264,695 was not actually at issue in any litigation up to the present. Notwithstanding this fact, a litigation between the present patent owner, the listed inventor, and Raymedica, Inc., has been settled and is no longer pending, as evidenced by the attached Stipulation for Dismissal With Prejudice and Order, signed by Judge David S. Doty on August 13, 2003 (Exhibit 1).

Accordingly, it is respectfully submitted that this application should not be subject to a bar against extensions of time to respond to Office Actions, and that the normal period for responding to an Office Action is warranted. Reconsideration is respectfully requested.

Claims 39 through 43, 48 and 49 have been amended to more particularly define the claimed subject matter. New claims 50 and 51 have been added to further define certain aspects. Support for the amendments and new claims may be found, e.g., at column 11, line 38, through column 12, line 10; column 15, line 52 through column 16, line 6; and Figs.14, 15A-15B, and 16A-16B of the specification. No new matter has been added by virtue of the present amendment and new claims. Entry of the amendment and new claims, and reconsideration of the rejections is respectfully requested.

Claims 39, 40, 43, 45 and 46 have been rejected under 35 U.S.C. §102(b) as anticipated by Bao et al. (U.S. Pat. No. 5,534,028). (column 5, lines 17-45). Reconsideration of the rejection is respectfully requested.

There is no indication in the cited portion of Bao et al. of a hydrogel intervertebral disc nucleus that undergoes anisotropic expansion and has a capacity to swell to a height which is greater than the height of a cavity defined between adjacent vertebrae. Anisotropic expansion is defined in the present specification, e.g., at column 10, lines 52-58, as “capability of a xerogel to expand due to its hydration, even in absence of an external load or any external restriction, in a selected direction or directions more than in other directions.”

Nowhere in Bao et al. is there a teaching or suggestion of such anisotropic expansion. The mere indication, in the cited portion, at column 5 of Bao et al., “that utilizing a two-piece prosthetic nucleus facilitates implantation, which is done with the hydrogel material in a dehydrated or unhydrated state” and that “in preferred embodiments one piece will be softer (less stiff) than the other,...” clearly does not describe “anisotropic expansion” as defined in the present specification and claims. Moreover, the indication, at column 5 of Bao et al., that,

After hydration in the disc, the hydrogel nucleus will generally be constrained tightly in the cavity from which the nucleus has been excised. The constraining forces are the restoring force of the stretched annulus fibers and the external force through the end-plates. The constraint from the annulus and the end-plates will generally restrict the movement of the hydrogel nucleus and prevent it from bulging and herniating from the cavity. However, in cases where previously herniated areas or incisions are particularly large, or where the restoring force of the stretched fibers is diminished due to fiber damage, bulging and herniation are diminished or prevented by the diminished lateral bulging of the present invention.

fails to teach or suggest that the hydrogel nucleus has a capacity to swell to a height which is greater than the height of the cavity between adjacent vertebrae. The cited portion merely indicates that the hydrogel nucleus will be “constrained tightly” in the cavity and “restrict movement” to prevent it from bulging or herniating from the cavity. This just means that it is held tightly in place and clearly does not teach or suggest a capacity to swell as recited in claim 39 and dependent claims 40, 43, 45 and 46.

Since anticipation requires the presence of all elements of a claim to be present within the confines of the Bao et al. reference, and since applicant has demonstrated that at least the foregoing elements are not taught or suggested in Bao et al., it is respectfully submitted that the rejection under 35 USC § 102(b) should be reconsidered and withdrawn.

Claims 39, 40 and 43-46 have been rejected under 35 USC § 102(b) as anticipated by Ray et al. (US Pat. Nos. 5,674,295). It is contended in the Office Action that Fig. 9 and column 4, lines 27-44 of Ray et al. disclose an implant member that undergoes anisotropic expansion and has a capacity to swell along the longitudinal axis which is greater than the space between adjacent vertebrae. Independent claim 39 and the dependent claims have been amended to more clearly indicate that the implant undergoes anisotropic expansion and has a capacity to swell to a height which is greater than the height of the cavity between adjacent vertebrae. It is clear that the constraining jacket 14 confines the Ray et al. prosthetic spinal disc nucleus to a particular shape, e.g., the pillow (see column 4, lines 22-23).

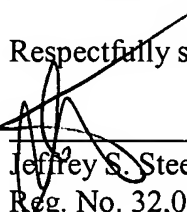
Nowhere in Ray et al. is there a teaching or suggestion of both anisotropic expansion and capacity to swell to a height which is greater than the height of the cavity between adjacent vertebrae. Since all elements of the claims must be present in Ray et al., and they are not, reconsideration and withdrawal of the rejection of claims 39, 40 and 43-46 is respectfully requested.

Claim 47 has been rejected under 35 USC § 103(a) as being unpatentable over Bao et al. The Office Action contends that it would have been an obvious matter of design choice to modify the hydrogel material of the Bao et al. reference because Applicant has not disclosed that having a xerogel material provides an advantage, is used for a particular purpose or solves a stated problem. As discussed above, Bao et al. neither teaches nor suggests a hydrogel nucleus that has a capacity to swell to a height which is greater than the height of the cavity between adjacent vertebrae. Moreover, at column 11, lines 48-56, of the present specification, certain advantages are discussed, e.g., it facilitates insertion and as the xerogel in the shape B and anisotropically dehydrated state has the shape optimized for insertion into the cavity through a small incision in the annulus. At column 12, lines 41-45, it states that "The deformed state is stable as long as the spinal nucleus implant hydrogel is partly or fully dehydrated and as long as temperature is below glass transition temperature and/or melting temperature of at least one polymer phase in the hydrogel." Accordingly, since advantages of the xerogel are specifically discussed in the specification, and Bao et al. fails to teach or suggest the above discussed features, the rejection of claim 47 should be reconsidered and withdrawn.

Applicant notes with appreciation, the Examiner's indication that claims 1-37 are allowed and that claims 41, 42, 48 and 49 were objected to, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. However, in view of the above remarks, it is respectfully submitted that all the claims are patentable over the cited references.

A good faith effort has been made to place the present application in condition for allowance. If there is any point requiring discussion prior to allowance, the Examiner is earnestly solicited to telephone the undersigned attorney for Applicants at the address below.

Respectfully submitted,

  
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Jeffrey S. Steen  
Reg. No. 32,063  
Attorney for Applicant

**Carter, DeLuca, Farrell & Schmidt, LLP**  
445 Broad Hollow Road, Suite 225  
Melville, New York 11747  
Tel.: (631) 501-5700  
Fax: (631) 501-3526  
JSS/mpl